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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/002,292	11/15/2001	Brian Ward	SGM 6938.1	2146

321 7590 10/20/2004

SENNIGER POWERS LEAVITT AND ROEDEL
ONE METROPOLITAN SQUARE
16TH FLOOR
ST LOUIS, MO 63102

EXAMINER	
HORLICK, KENNETH R	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/002,292	WARD ET AL.	
	Examiner	Art Unit	
	Kenneth R Horlick	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 July 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *159-259* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *229-259* is/are allowed.

6)☒ Claim(s) *159-185,212-214 and 223-227* is/are rejected.

7)☒ Claim(s) *186-211,215-222 and 228* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/23/04; 2/5/04.* (5 pages)
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 159-185, 212-214, and 223-227 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramsay Shaw et al. (US 5,683,869).

These claims are drawn to kits comprising a dNTP mixture, wherein said mixture comprises four unmodified dNTPs and at least one modified dNTP which when incorporated into a polynucleotide imparts exonuclease resistance.

As an initial matter, it is noted that in kit claims written instructions and other "intended use"-type limitations are not given patentable weight.

Ramsay Shaw et al. disclose methods comprising the use of a dNTP mixture comprising at least one modified nucleotide, said nucleotide conferring exonuclease resistance when incorporated into a polynucleotide. Said methods include the use of

the enzyme exonuclease III. Some of the dNTP mixtures comprise two or three such modified nucleotides. In column 1, prior art is cited teaching that such dNTP mixtures comprising 5-alpha thio-modified dNTPs were known in the art, and the main disclosure relates to 5-alpha borano-modified dNTPs. See columns 1-10, 15, 17-19, and example 7 in columns 24-25.

Ramsay Shaw et al. do not disclose kits comprising said dNTP mixtures.

Combination of reagents into kits for the convenience of practicing methods which require such reagents was indisputably well known and common knowledge in the art at the time of the invention.

One of ordinary skill in the art would have been motivated to make kits comprising various dNTP mixtures comprising modified dNTPs capable of conferring exonuclease resistance to polynucleotides (such as alpha-thio or alpha-borano-modified dNTPs) because such kits would have clearly been useful in carrying out the methods of Ramsay Shaw et al. It is emphasized that any differences between the method of Ramsay Shaw et al. and that of the instant disclosure are not relevant here because the claims in question are kit claims, and any motivation found in the prior art for making a claimed kit is applicable, even if for a different purpose. As far as the claims requiring various concentrations of modified versus unmodified dNTPs, this is considered to be routine optimization of reaction parameters, which is understood not to contribute to unobviousness in the absence of evidence to the contrary. Besides, Example 2 in columns 17-19 teaches optimization of modified dNTP incorporation using kinetic analysis, including considerations of the ratio between modified/unmodified dNTPs. It

would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to make and use the claimed kits.

2. With respect to the above rejection, the arguments of the response filed 07/16/04 have been fully considered, but are not found persuasive.

First, arguments are presented regarding patentable weight for written "instructions". The examiner has discussed this topic in great detail in the past with TC1600 Biotech Practice Specialists, and the conclusion has been that the Office is not aware of any case law pertaining to written instructions as a separate component in a kit claim. As far as the examiner is aware, the case law referred to in the response deals with printed matter which directly modifies a product being claimed, such as printed matter on a claimed object. In the kit claims under consideration, however, the printed matter in the form of instructions is a separate component which in no way modifies any actual product or reagent in the kit, and thus the printed matter only relates to intended use for the kit in a certain method. It is the position of the Office that "intended use" limitations do not carry weight in product claims (such as kit claims). As this policy has been made clear to the examiner, if applicants wish to pursue this matter further it is suggested that a TC1600 Biotech Practice Specialist be contacted.

Regarding the arguments as to specific ratios in the claims, it is pointed out that in column 9 of Ramsay Shaw et al. a ratio of modified dNTP: unmodified dNTP of 2 is disclosed, which is in the range of the claims. Ratios of less than 1 (i.e., 1:10 and 1:5) are disclosed as well, which are also in the range of some of the claims.

3. Claims 229-259 are allowable. Claims 186-211, 215-222, and 228 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth R Horlick whose telephone number is 571-272-0784. The examiner can normally be reached on Monday-Thursday 6:30AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kenneth R. Horlick, Ph.D.
Kenneth R Horlick
Primary Examiner
Art Unit 1637

10/05/04